

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

1. (currently amended) A method of diagnosing or determining the risk of developing gastric cancer in a subject with a *Helicobacter* infection, including:

- a) determination of IgG2 anti-*H. pylori* antibody level in the subject; and
- b) comparison of the IgG2 anti-*H. pylori* antibody level with a predetermined control IgG2 anti-*H. pylori* antibody level, wherein a reduction in the level of IgG2 anti-*H. pylori* antibody in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer,

wherein the predetermined control IgG2 anti-*H. pylori* antibody level represents about the average level of IgG2 anti-*H. pylori* antibody in subjects infected with *Helicobacter* or about the average level of IgG2 anti-*H. pylori* antibody in subjects infected with *Helicobacter* who are not suffering from gastric cancer.

- 2-22. (canceled)

23. (currently amended) A method of diagnosing or determining the risk of developing gastric cancer in a subject with a *Helicobacter* infection, including:

- a) determination of γ IFN level in the subject;
- b) comparison of the γ IFN level with a predetermined control γ IFN level, wherein a reduction in the level of γ IFN in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer,

wherein the predetermined control γ IFN level represents about the average level of γ IFN in subjects infected with *Helicobacter* or about the average level of γ IFN in subjects infected with *Helicobacter* who are not suffering from gastric cancer.

24. (currently amended) A method of diagnosing or determining the risk of developing gastric cancer in a subject with a *Helicobacter* infection, including:
- a) determination of IL-4 level in the subject;
 - b) comparison of the IL-4 level with a predetermined control IL-4 level, wherein an elevation in the level of IL-4 in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer,
wherein the predetermined control IL-4 level represents about the average level of IL-4 in subjects infected with *Helicobacter* or about the average level of IL-4 in subjects infected with *Helicobacter* who are not suffering from gastric cancer.
25. (currently amended) A method of diagnosing or determining the risk of developing gastric cancer in a subject with a *Helicobacter* infection, including ~~a combination of the method according to claim 1 and a method according to claim 23~~ further comprising the steps of
- c) determination of γ IFN level in the subject; and
 - d) comparison of the γ IFN level with a predetermined control γ IFN level, wherein a reduction in the level of γ IFN in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer.
26. (currently amended) A method of diagnosing or determining the risk of developing gastric cancer in a subject with a *Helicobacter* infection, including ~~a combination of the method according to claim 1 and a method according to claim 24~~ further comprising the steps of
- c) determination of IL-4 level in the subject; and
 - d) comparison of the IL-4 level with a predetermined control IL-4 level, wherein an elevation in the level of IL-4 in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer.

27. (currently amended) The method of claim 25 further comprising ~~a method according to claim 24~~ the steps of
- e) determination of IL-4 level in the subject; and
 - f) comparison of the IL-4 level with a predetermined control IL-4 level, wherein an elevation in the level of IL-4 in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer.
28. (currently amended) A method of diagnosing or determining the risk of developing gastric cancer in a subject with a *Helicobacter* infection, including ~~a combination of the method according to claim 23 and a method according to claim 24~~ further comprising the steps of
- g) determination of IL-4 level in the subject; and
 - h) comparison of the IL-4 level with a predetermined control IL-4 level, wherein an elevation in the level of IL-4 in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer.
29. (previously presented) A method according to any one of claims 1, 23 or 24 wherein the *Helicobacter* infection is a *Helicobacter pylori* infection.
30. (previously presented) A method according to claim 1 wherein the IgG2 anti-*H. pylori* antibody level is determined by detection of the level in a sample of biological fluid.
31. (previously presented) A method according to claim 23 wherein the γ IFN level is determined by detection of the level in a sample of biological fluid.
32. (previously presented) A method according to claim 24 wherein the IL-4 level is determined by detection of the level in a sample of biological fluid.
33. (previously presented) A method according to claim 1 wherein the IgG2 anti-*H. pylori* antibody level is determined by detection of the level in a biological fluid selected from the group consisting of blood, saliva and gastric fluid.
34. (previously presented) A method according to claim 23 wherein the γ IFN level is determined by detection of the level in a biological fluid selected from the group consisting of blood, saliva and gastric fluid.
35. (previously presented) A method according to claim 24 wherein the IL-4 level is determined by detection of the level in a biological fluid selected from the group

consisting of blood, saliva and gastric fluid.

36. (currently amended) A method according to claim 1 wherein the determination of the IgG2 anti-*H. pylori* antibody level either simultaneously provides, or can be performed simultaneously with, a method which provides an indication of *H. pylori* gastrointestinal condition status selected from the group consisting of esophagus reflux, chronic gastritis, dysplasia and gastric cancer.
37. (currently amended) A method according to claim 23 wherein the determination of the γ IFN level either simultaneously provides, or can be performed simultaneously with, a method which provides an indication of *H. pylori* gastrointestinal condition status selected from the group consisting of esophagus reflux, gastritis, dysplasia and gastric cancer.
38. (currently amended) A method according to claim 24 wherein the determination of the IL-4 level either simultaneously provides, or can be performed simultaneously with, a method which provides an indication of *H. pylori* gastrointestinal condition status selected from the group consisting of esophagus reflux, gastritis, dysplasia and gastric cancer.
39. (previously presented) A method according to claim 1 wherein the IgG2 anti-*H. pylori* antibody level is detected by a near-subject assay.
40. (previously presented) A method according to claim 23 wherein the γ IFN level is detected by a near-subject assay.
41. (previously presented) A method according to claim 24 wherein the IL-4 level is detected by a near-subject assay.
42. (previously presented) A method according to claim 1 wherein the IgG2 anti-*H. pylori* antibody level is determined by an antibody assay.
43. (currently amended) A method according to claim 23 wherein the γ IFN level is determined by an anti- γ IFN antibody assay.
44. (currently amended) A method according to claim 24 wherein the IL-4 level is determined by an anti-IL-4 antibody assay.
45. (previously presented) A method according to claim 1 wherein the IgG2 anti-*H. pylori* antibody level is determined by ELISA.
46. (previously presented) A method according to claim 23 wherein the γ IFN level is

determined by ELISA.

47. (previously presented) A method according to claim 24 wherein the IL-4 level is determined by ELISA.
48. (currently amended) A method of predicting the risk of, or diagnosing, gastric cancer in a subject having a *Helicobacter* infection by
 - a) determining the frequency of IgG2 anti-*H. pylori* antibody-producing cells and/or γ IFN-producing cells and/or IL-4-producing cells in the subject's blood; and
 - b) comparison of the frequency of IgG2 anti-*H. pylori* antibody-producing cells and/or γ IFN-producing cells and/or IL-4-producing cells in the subject's blood with a predetermined control level, wherein a reduction in the level of IgG2 anti-*H. pylori* antibody-producing cells and/or γ IFN-producing cells and/or an elevation in IL-4-producing cells in the subject's blood indicates the presence of gastric cancer or an increased risk of developing gastric cancer.
49. (previously presented) A method according to claim 48 wherein the blood is purified to provide an enriched white blood cell population.
50. (previously presented) A method according to claim 48 wherein the blood is purified to provide an enriched white blood cell population and the white blood cell population is further fractionated to obtain specific cell populations.
51. (previously presented) A method according to claim 48 wherein when the frequency of IgG2 anti-*H. pylori* antibody-producing cells is determined, the IgG2 anti-*H. pylori* antibody-producing cells are stimulated with *H. pylori* antigen prior to determination of the frequency of IgG2 anti-*H. pylori* antibody-producing cells.
52. (previously presented) A method according to claim 48 wherein when the frequency of γ IFN-producing cells is determined, the γ IFN-producing cells are stimulated with *H. pylori* antigen prior to determination of the frequency of γ IFN-producing cells.
53. (previously presented) A method according to claim 48 wherein when the frequency of IL-4-producing cells is determined, the IL-4-producing cells are stimulated with *H. pylori* antigen prior to determination of the frequency of IL-4-producing cells.
54. (currently amended) A method of predicting the risk of, or diagnosing, gastric cancer in a subject having a *Helicobacter* infection by

- a) determining the frequency of IgG2 anti-*H. pylori* antibody-producing cells and/or γIFN-producing cells and/or IL-4-producing cells in the subject's gastric mucosa; and
 - b) comparison of the frequency of IgG2 anti-*H. pylori* antibody-producing cells and/or γIFN-producing cells and/or IL-4-producing cells in the subject's gastric mucosa with a predetermined control level, wherein a reduction in the level of IgG2 anti-*H. pylori* antibody-producing cells and/or γIFN-producing cells and/or an elevation in IL-4-producing cells in the subject's gastric mucosa indicates the presence of gastric cancer or an increased risk of developing gastric cancer
55. (previously presented) A method according to claim 54 wherein the cells are derived from a biopsy sample.
56. (currently amended) A method according to claim 54 wherein the frequency of IgG2 anti-*H. pylori* antibody-producing cells and/or γIFN-producing cells and/or IL-4-producing cells is determined by flow cytometry.
57. (new) A method of diagnosing gastric cancer in a subject with a *Helicobacter* infection and gastric cancer, including:
- a) determination of IgG2 anti-*H. pylori* antibody level in the subject; and
 - b) comparison of the IgG2 anti-*H. pylori* antibody level with a predetermined control IgG2 anti-*H. pylori* antibody level, wherein a reduction in the level of IgG2 anti-*H. pylori* antibody in the subject compared to the control indicates the presence of gastric cancer.

58. (new) A method of diagnosing gastric cancer in a subject with a *Helicobacter* infection and gastric cancer, including:

- a) determination of γ IFN level in the subject; and
- b) comparison of the γ IFN level with a predetermined control γ IFN level, wherein a reduction in the level of γ IFN in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer.

59. (new) A method of diagnosing gastric cancer in a subject with a *Helicobacter* infection and gastric cancer, including:

- a) determination of IL-4 level in the subject; and
- b) comparison of the IL-4 level with a predetermined control IL-4 level, wherein an elevation in the level of IL-4 in the subject compared to the control indicates the presence of gastric cancer or an increased risk of developing gastric cancer.